

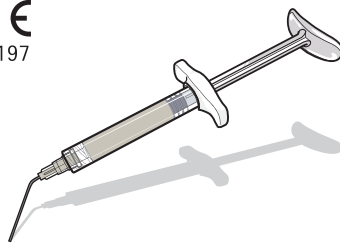


CE
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ROOT CANAL FILLING MATERIAL
ENDOSEAL[®] MTA
Mineral Trioxide Aggregate

PREMIXED INJECTABLE PASTE

2 g Syringe X 1 EA + 24 gauge Tip X 20 EA + Storage Cap X 5 EA
3 g Syringe X 1 EA + 24 gauge Tip X 20 EA + Storage Cap X 5 EA



Do not reuse the cap.
Not sealable if removed once.

PRODUCT DESCRIPTION

ENDOSEAL MTA is an endodontic sealer based on MTA, providing a biocompatible and effective root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal, including accessory and lateral canals. The product is eugenol-free and will not impede adhesion inside the root canal.

1. Hydrophilic properties
2. Insolubility
3. Excellent sealing properties
4. High flowability : injection syringes are easy to manipulate and also to fill accessory and lateral canals.
5. Biocompatibility : tissue recovers without causing inflammatory reaction
6. Dimensional stability
7. High Radiopacity
8. Easy removal : simple retreatment, especially when using a master cone with the product

INDICATION FOR USE

Permanent root canal obturation

- **Intended use**
ENDOSEAL MTA is developed for root canal filling and root perforation repair, effectively preventing periapical tissue irritation as well as secondary infection.
- **Intended user**
The product is only to be used in a clinical or hospital environment by qualified dentists.
- **Application Field**
Obturation of the enlarged, shaped, cleaned and disinfected root canal.
- **Patient population**
- All age group
All patients requiring root canal procedures in teeth of the permanent dentition or in teeth of the primary dentition when there is no permanent successor.
- **Single use**

CONTRAINDICATION

Do not use in patients who are allergic to any of the product's ingredients.

COMBINATION WITH THE DEVICE

Injected gutta-percha material or Core-carriers master cone.

COMPOSITION

Natural Pure Cement, Zirconium Dioxide, Bismuth Trioxide, n-Methyl-2-Pyrrolidone and thickener
* N-Methyl-2-pyrrolidone (NMP) : contain in 23.19%, CMR Category 1B – toxic to reproduction

PERFORMANCE CHARACTERISTICS (According to ISO 6876)

- Setting time : no longer than 12.3 min + 10%
- Flow : above 17 mm
- Film thickness : below 50 µm
- Solubility : below 3.0%
- Radiopacity : The same radiopacity as that of aluminum of above 3 mm in thickness

PRECAUTION FOR USE

1. WARNING

- 1) Do not use in patients with allergic reaction to chemicals.
- 2) For dentists use only.
- 3) If large amounts of material are pushed into the mandibular canal, remove it with surgical method immediately. (according to state-of-the-art policy)
- 4) Do not use in pregnant women or women who may become pregnant.

2. GENERAL PRECAUTIONS

- 1) Always check if the package is damaged before use.
- 2) Do not use for other purposes.
- 3) Keep in a sealed container before use to prevent chemical reaction by carbon dioxide with moisture in the air.

- 4) Do not contact unhardened product with the skin or mucous membrane. If contact occurs, rinse with large amounts of water immediately.
- 5) Wear protective gloves, mask and glasses.
- 6) The product must be stored at room temperature avoiding high temperature and humidity.
- 7) Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children or adolescents.

3. APPLICATION PRECAUTIONS

- 1) Make sure that the product comes out smoothly through the tip.
- 2) The root canal must be dried before filling.
- 3) There is a possibility that a large amount of sealer may go beyond the root apex if there is external resorption due to the apical lesion. In this case, the application of ultrasonic waves to the master cone should be omitted.

4. INTERACTIONS

- 1) The product should be used immediately after replacing the 24 gauge tip because it will be hardened when in contact with air.
- 2) If there is no apical lesion but there is apical stop, it is recommended to use ultrasonic device to make the root canal filling evenly.
- 3) In order to deliver ultrasonic waves, apply the device to tweezers holding a master cone.

ADVERSE REACTIONS

No adverse reaction has been reported to date.

* Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

STEP BY STEP INSTRUCTION

1. PREPARATION PRIOR TO USE

- 1) Always check if the package is damaged before use.
- 2) The tip should be changed with a new one prior to use, and make sure that the sealer comes out smoothly.

2. DIRECTION FOR USE

1) Indirect pulp capping When the root canal is filled with sealer and master cones

- ① After root canal preparation is completed, disinfect and dry the root canal.
- ② Choose the master cone.
- ③ Replace the 24 gauge tip.
- ④ Do not insert a 24 gauge tip deeper than apical third of the root canal.
- ⑤ Inject the sealer into root canal until it is seen at the root canal orifice.
- ⑥ Insert the master cone into the root canal push it to the apical stop softly.
- ⑦ Hold the master cone with tweezers and apply ultrasonic waves.
- ⑧ There is a possibility that a large amount of sealer may go beyond the root apex, if there is external resorption due to the apical lesion. In this case, the application of ultrasonic waves to the master cone should be omitted.
- ⑨ Cut the master cone at the root canal orifice.
- ⑩ Take radiographs.

2) When the root canal is filled with sealer

- ① After root canal preparation is completed, disinfect and dry the root canal.
- ② Replace the 24 gauge tip.
- ③ Check if the sealer releases smoothly from the 24 gauge tip.
- ④ Inject the sealer into root canal.
- ⑤ Take radiographs.

3) Removal of sealer

When the sealer is filled with the master cone together in the root canal, it is removed with the conventional removal method of the master cone.

INSTRUCTION FOR STORAGE

1. The product should be stored at room temperature avoiding high temperature and humidity.
2. The product use immediately after replacing the 24 gauge tip because it will be hardened when in contact with air.
3. A new 24 gauge tip replaces it in next use.
4. After use do not recap the used 24 gauge tip, twist the storage cap provided with the product tightly onto the syringe head.
5. Once the gray cap, which was initially fastened to the syringe, is separated, it will not be sealed even if it is fastened again. It must be sealed using the enclosed storage cap.
6. Place syringe with the storage cap in the provided pouch. Seal the pouch completely.
7. Tighten the storage cap immediately after use to minimize the product from contamination and infection during storage.

SHELF LIFE

2 years from date of manufacture.

DISPOSAL

Adhere to national laws and recommendations of local authorities for proper disposal.

SYMBOL

	Non-sterile		Do not use if package is damaged
	Temperature limit		Keep away from sunlight
	Consult instruction for use		Keep away from rain
	Batch code		Do not re-use
	Use by date		Caution
	Date of manufacture		Medical device
	Manufacturer		Unique Device Identifier
	Importer		Authorized representative in the European Union
	Contains hazardous substances		

We just mimic nature

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